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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,320	10/20/2003	Susan A. Kingsman	674523-2030	4549
20999 7590 09/19/2007 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER MONTANARI, DAVID A	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 09/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/690,320

Applicant(s)

KINGSMAN ET AL.

Examiner

David Montanari

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/9/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 13, 18-24, 31, 34 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 13, 18-24, 31, 34 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants arguments and amendments filed 7/9/2007 have been entered.
2. Claims 12, 13 and 24 are amended.
3. Claims 1-11, 14-17, 25-30, 32, 33 and 35-39 are cancelled.
4. The rejection of claim 12 under 35 USC 101 is withdrawn.
5. Claims 12, 13, 18-24, 31, 34 and 40 are examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 18-24, 31, 34 and 40 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of transducing a target mammalian adipose tissue cell *in vitro* with a lentiviral vector pseudotyped with the VSV-G protein and comprising at least one nucleotide sequence of interest, does not reasonably provide enablement for a method of transducing or delivering to a target mammalian adipose tissue cell *in vivo* a lentiviral vector pseudotyped with the VSV-G protein to treat any disease associated with adipose tissue metabolism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for reasons of record in the office action mailed 4/10/2007 and the office action mailed 6/21/2006.

Response to Arguments

Applicants argue in amendment filed 7/9/2007 that the claims have been amended to reflect the scope deemed enabled by the Examiner. This argument is not persuasive.

While Applicant has amended the claims to recite that mammalian adipose tissue is transduced and that the vector now comprises pseudotyping with the VSV-G protein, not all of the claims are enabled. Applicant is directed to the arguments set forth in the office action mailed on 6/21/2006 at pages 4-7. As taught in the specification, the claimed invention is envisioned as a potential method of therapy (pg. 2, lines 5-7) in adipose tissue. This issue still remains unresolved and Applicant has not provided any arguments directed to the specific issue of treatment which has been discussed in the above office action. Thus for reasons of record and above the rejection is maintained.

Further the scope rejection above has been amended to recite that the claimed methods are enabled for the *in vitro* practice of the method only. In the office action mailed on 6/21/2006, the scope rejection detailed the unpredictability of practicing the claimed method *in vivo*. Applicants response filed on 9/20/2006 (pg. 5, parag. 2) provided no arguments towards the specific issues raised over the *in vivo* application of the claimed method. As discussed in the office action mailed on 6/21/2006, methods of treatment are one of the intended uses of the claimed method, though there is no specific treatment language recited in the instant claims, claims 13 and 24 embrace the therapeutic use of a lentiviral vector pseudotyped with the VSV-G protein and comprising at least one nucleotide of interest. Accordingly the claimed methods are now limited to *in vitro*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12 remains rejected under 35 U.S.C. 102(b) as being anticipated by Dewhurst et al. (2000, *Frontiers in Bioscience*, Vol. 5, pgs. 30-49), and further evidenced by Hazan et al. (2002, *FASEB*, Vol. 16, pgs. 1254-1256) for reasons of record in the office action mailed 4/10/2007.

Response to Arguments

Applicants argue in amendment filed 7/9/2007 that neither reference cited in the 102(b) rejection teaches a lentiviral vector pseudotyped with at least part of a VSV-G protein to transduce mammalian adipose tissue cells. This argument is not persuasive.

Claim 12 is directed to an isolated mammalian adipose tissue cell. This cell has been transduced with a lentiviral vector, and that vector has been pseudotyped with VSV-G. The adipose tissue cell transduced with a lentiviral vector as taught by Dewhurst et al. would be indistinguishable from the claimed transduced adipose tissue cell. Pseudotyping viral vectors is well known in the art as a means to gain viral entry into particular cell type. While VSV-G is recited in the claims, it does not impart any unique or specific function to the viral vector other than to gain entry into the target mammalian adipose tissue cell. The adipose cell transduced with the lentiviral vector as taught in Dewhurst et al., again is indistinguishable from the transduced

Art Unit: 1632

adipose tissue cell that is claimed. Thus for reasons of record and above the rejection is maintained.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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